K110533(1/2)

510(k) Summary

MAY 19 2011

Sponsor	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Karen Ariemma Project Manager, Regulatory Affairs/Regulatory Compliance Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5718
Date Prepared:	February 23, 2011
Proprietary Name:	Stryker® Patient Specific Cutting Guides
Common Name:	Cutting Guide
Classification Name:	21 CFR §888.3560 Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Smith & Nephew Visionaire System, K082358

Device Description: The Stryker® Patient Specific Cutting Guides are single-use, disposable, cutting guides designed and manufactured from patient imaging data (MRI/CT). The cutting guides are used to aid the surgeon intra-operatively in making the initial distal femoral and the initial proximal tibial bone cuts during a total knee arthroplasty surgery. The cutting guides also establish the references for component orientations. The cutting guides are manufactured from polyoxymethylene per ASTM F1855.

The Stryker® Patient Specific Cutting Guides are intended for use with the Triathlon® Knee System (Cruciate Retaining (CR), Posterior Stabilized (PS) and Condylar Stabilizing (CS)) determined substantially equivalent via the following 510(k)s K031729, K040267, K042993, K051146, K051380, K053514, K062037, K061251, K063423, and K072575.

The accessory Triathlon® Extra-medullary (EM) Universal Goniometer is available for the surgeon to use intra-operatively to check the position of the femoral and tibial components. The goniometer mates with the saw slots on both the femoral and tibial guides for use in referencing the cuts with anatomic landmarks prior to resection of the bone. The accessory Triathlon® EM Universal Goniometer is made from Stainless Steel per ASTM A564.

Intended Use: The Stryker® Patient Specific Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee arthroplasty components intraoperatively and in guiding the marking of bone before cutting.
Indications: The Stryker® Patient Specific Cutting Guides are intended for use with the CR, PS and CS components of the Triathlon® Knee System. The indications for use of the Triathlon Knee System when used with the Stryker Patient Specific Cutting Guides are:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed reconstruction procedures which did not involve the implantation of hardware on the condylar surfaces

Additional Indications for Posterior Stabilized (PS):

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

The Stryker® Patient Specific Cutting Guides are intended for single use only.

Summary of Technologies: Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the predicate device.

Non-Clinical Testing: A cadaveric assessment was undertaken to quantify the accuracy of the Stryker Patient Specific Knee Cutting Guides relative to the pre-operative plan in a cadaveric model and compare the placement accuracy achieved with the use of Stryker Patient Specific Knee Cutting Guides is comparable to conventional jig based instrumentation. The verification utilized cadaveric data and all investigations were conducted in conformity with ethical principles of research.

Detailed software verification and validation were performed per FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Clinical Testing: A clinical research study was performed to quantify the accuracy and the repeatability of measurements obtained from a new magnetic resonance imaging (MRI) protocol. The study also measured and compared the mechanical alignment angle of the knee obtained through MRI scans and long standing radiograph images. A strong co-relationship between the long leg x-ray and augmented MRI scanning was demonstrated.

Conclusion: The Stryker Patient Specific Cutting Guides are substantially equivalent to the predicate device identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Karen Ariemma
Project Manager, Regulatory Affairs/Regulatory Compliance
325 Corporate Drive
Mahwah, New Jersey 07430

MAY 19 2011

Re: K110533
Trade/Device Name: Stryker® Patient Specific Cutting Guides
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OOG
Dated: February 23, 2011
Received: February 24, 2011

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110533

Device Name: Stryker ® Patient Specific Cutting Guides

Indications for Use:

The Stryker® Patient Specific Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee arthroplasty components intraoperatively and in guiding the marking of bone before cutting.

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110533